

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

IN THE MATTER OF:

**Leica Biosystems
5205 Route 12
Richmond, IL 60071**

ATTENTION:

**Dow Carter
Senior EHS Manager**

Request to Provide Information Pursuant to the Clean Air Act

The U.S. Environmental Protection Agency is requiring Leica Biosystems (Leica or you) to submit certain information about the facility at 5205 Route 12, Richmond, Illinois. Appendix A provides the instructions needed to answer this information request, including instructions for electronic submissions. Appendix B and Appendix C specify the information that you must submit. You must send this information to us according to the schedules contained in each appendix.

We are issuing this information request under Section 114(a) of the Clean Air Act (the CAA), 42 U.S.C. § 7414(a). Section 114(a) authorizes the Administrator of EPA to require the submission of information. The Administrator has delegated this authority to the Director of the Air and Radiation Division, Region 5.

Leica owns and operates an emission source at the Richmond, Illinois facility. We are requesting this information to determine whether your emission source is complying with the Illinois State Implementation Plan and the CAA.

Leica must send all required information to:

Attn: Compliance Tracker, AE-17J
Air Enforcement and Compliance Assurance Branch

U.S. Environmental Protection Agency
Region 5
77 W. Jackson Boulevard
Chicago, Illinois 60604

Leica must submit all required information under an authorized signature with the following certification:

I certify under penalty of law that I have examined and am familiar with the information in the enclosed documents, including all attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are, to the best of my knowledge and belief, true and complete. I am aware that there are significant penalties for knowingly submitting false statements and information, including the possibility of fines or imprisonment pursuant to Section 113(c)(2) of the Clean Air Act and 18 U.S.C. §§ 1001 and 1341.

As explained more fully in Appendix D, you may assert a claim of business confidentiality under 40 C.F.R. Part 2, Subpart B for any part of the information you submit to us. Information subject to a business confidentiality claim is available to the public only to the extent, and by means of the procedures, set forth at 40 C.F.R. Part 2, Subpart B. If you do not assert a business confidentiality claim when you submit the information, EPA may make this information available to the public without further notice. You should be aware, moreover, that pursuant to Section 114(c) of the CAA and 40 C.F.R. § 2.301(a) and (f), emissions data, standards and limitations are not entitled to confidential treatment and shall be made available to the public notwithstanding any assertion of a business confidentiality claim. Appendix D provides additional information regarding the meaning and scope of the term "emissions data."

This information request is not subject to the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.*, because it seeks collection of information from specific individuals or entities as part of an administrative action or investigation.

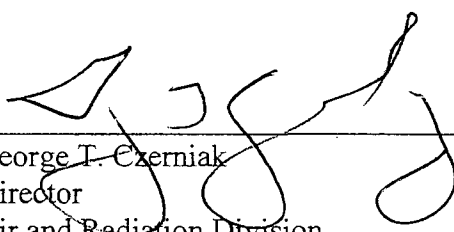
We may use any information submitted in response to this request in an administrative, civil or criminal action.

Failure to comply fully with this information request may subject Leica to an enforcement action under Section 113 of the CAA, 42 U.S.C. § 7413.

You should direct any questions about this information request to Scott Connolly at 312 886-1493 or at connolly.scott@epa.gov.

Date

3/7/16


George T. Czerniak
Director
Air and Radiation Division

Appendix A

When providing the information requested in Appendix B and Appendix C, use the following instructions and definitions.

Instructions

1. Provide a separate narrative response to each question and subpart of a question set forth in Appendix B.
2. Precede each answer with the number of the question to which it corresponds and at the end of each answer, identify the person(s) who provided information used or considered in responding to that question, as well as each person consulted in the preparation of that response.
3. Mark on each document produced, or in some other reasonable manner, the number of the question to which it corresponds.
4. When a response is provided in the form of a number, specify the units of measure of the number in a precise manner.
5. Where information or documents necessary for a response are neither in your possession nor available to you, state in your response why the information or documents are not available or in your possession, and identify any source that either possesses or is likely to possess the documents or information.
6. If information not known or not available to you as of the date of submission later becomes known or available to you, you must supplement your response. Moreover, should you find at any time after the submission of your response that any portion of the submitted information is false or incorrect, you must notify EPA as soon as possible.

Electronic Submissions

To aid in our electronic recordkeeping efforts, we request that you provide all documents responsive to this information request in an electronic format according to paragraphs 1 through 6, below. These submissions are in lieu of hard copy.

1. Provide all responsive documents in Portable Document Format (PDF) or similar format, unless otherwise requested in specific questions. If the PDFs are scanned images, perform at least Optical Character Recognition (OCR) for "image over text" to allow the document to be searchable. Submitters providing secured PDFs should also provide unsecured versions for EPA use in repurposing text.
2. When specific questions request data in electronic spreadsheet form, provide the data and corresponding information in editable Excel or Lotus format, and not in image format. If Excel or Lotus formats are not available, then the format should

allow for data to be used in calculations by a standard spreadsheet program such as Excel or Lotus.

3. Provide submission on physical media such as compact disk, flash drive or other similar item.
4. Provide a table of contents for each compact disk or flash drive containing electronic documents submitted in response to our request so that each document can be accurately identified in relation to your response to a specific question. *We recommend the use of electronic file folders organized by question number.* In addition, each compact disk or flash drive should be labeled appropriately (e.g., Company Name, Disk 1 of 4 for Information Request Response, Date of Response).
5. Documents claimed as confidential business information (CBI) must be submitted on separate disks/drives apart from the non-confidential information. This will facilitate appropriate records management and appropriate handling and protection of the CBI. Please follow the instructions in Appendix D for designating information as CBI.
6. Certify that the attached files have been scanned for viruses and state what program was used.

Definitions

All terms used in this information request have their ordinary meaning unless such terms are defined in the CAA, 42 U.S.C. §§ 7401 *et seq.*

1. The terms “document” and “documents” shall mean any object that records, stores, or presents information, and includes writings, memoranda, records, or information of any kind, formal or informal, whether wholly or partially handwritten or typed, whether in computer format, memory, or storage device, or in hardcopy, including any form or format of these. If in computer format or memory, each such document shall be provided in translation to a form useable and readable by EPA, with all necessary documentation and support. All documents in hard copy should also include attachments to or enclosures with any documents.
2. The terms “relate to” or “pertain to” (or any form thereof) shall mean constituting, reflecting, representing, supporting, contradicting, referring to, stating, describing, recording, noting, embodying, containing, mentioning, studying, analyzing, discussing, evaluating, or relevant to.
3. The term “representative conditions” shall mean the operating conditions specific to the source that represent performance based on normal operating conditions.

Appendix B

Leica must respond to this information request by performing testing at its facility in Richmond, Illinois ("the facility") pursuant to Section 114(a) of the CAA, 42 U.S.C. § 7414(a). Leica must submit an emission test plan, conduct emissions testing and submit all other information requested in accordance with the schedule specified below:

Submit Testing Protocol(s)	Within 45 days of receipt of this request
Notification of Intent to Test	Not less than 21 days before testing
Complete Testing	Within 90 days of receipt of this request
Submit Testing Report	Within 30 days of completion of testing

1. Within 90 days after the receipt of this request, Leica must perform an emissions test on blending tanks while 100% xylene constituents are being used. The test must incorporate the combined emissions from the 5 blending tanks. The emissions test will determine the hourly emission rate of xylene from the stack associated with the blending tanks. If multiple stacks are associated then the testing will be conducted on each of the associated stacks.
2. During the testing pursuant to Item 1. above, Leica shall operate the associated emissions units and process equipment at the highest operational capacity Leica has achieved in the past 2 years, under representative conditions.
3. Within 45 days after receipt of this request, Leica shall submit to EPA the proposed testing protocol(s) that completely describes the methods and procedures for testing at each unit, including all relevant operating parameters. Leica shall conduct the required testing under a protocol approved in advance by EPA. The protocol shall address the requirements of Item 1 of this information request. Leica shall conduct testing in accordance with EPA Methods 1, 2, 3, and 18. You may submit the protocol by email.
4. At least 21 days prior to the planned test date(s), Leica shall submit notification to EPA of its intent to perform emission testing. You may submit this notice by e-mail.
5. Within 30 days after completion of the tests required by this information request, Leica shall submit a complete report of the emissions testing on its facility, including, at a minimum, the following:
 - a. Summary of Results
 1. Results of the above specified emission tests;
 2. Process and control equipment data related to determining compliance;
 3. Discussion of test errors;

4. Discussion of any deviations from the reference test methods as set forth in the approved testing protocol;
 5. Raw material used during the test; and
 6. Finished goods production data.
- b. Facility Operations
1. Description of the process and control equipment in operation;
 2. Operating parameters of the process units, and related equipment at the time of the test; and
 3. Facility operating parameters that demonstrate that the process units were operated at maximum production rates at the time of the test.
- c. Sampling and Analytical Procedures
1. Sampling port location(s) and dimensions of cross-section;
 2. Sampling point description, including labeling system;
 3. Brief description of sampling procedures, including equipment and diagram;
 4. Description of sampling procedures (planned and accidental) that deviated from any standard method as set forth in the approved testing protocol;
 5. Brief description of analytical procedures, including calibration;
 6. Description of analytical procedures (planned or accidental) that deviated from any standard method as set forth in the approved testing protocol; and
 7. Quality control/quality assurance procedures, tests, and results.
- d. Appendix
1. Complete results with example calculations;
 2. Raw field data (original, not computer printouts);
 3. Laboratory report, with signed chain-of-custody forms;
 4. Calibration procedures and results;
 5. Raw process and control equipment data, signed by plant representative;
 6. Test log;
 7. Project participants and titles; and
 8. Related correspondence

Appendix C

Leica must submit the following information about its facility in Richmond, Illinois, pursuant to Section 114(a) of the CAA, 42 U.S.C. § 7414(a), within 30 calendar days of its receipt of this letter.

1. Provide a copy of each air permit issued to Leica for the Facility by Illinois Environmental Protection Agency (IEPA) from January 1, 2006 to the present. The air permits include but are not limited to, operating permits, construction permits, and permit amendments.
2. Provide a copy of all permit applications that were submitted to IEPA to obtain permits issued to the facility since January 1, 2006. Include emissions calculations used to establish permitted limits.
3. Provide a diagram of the ventilation-and-control systems at the facility that control emissions and/or duct emissions at the atmosphere. Include all emission sources and points where emissions enter the atmosphere.
4. Provide in an Excel spreadsheet or compatible format, records on each process using formaldehyde, methanol, or xylene, including but not limited to the following, from January 1, 2012 to the present.
 - a. daily usage of each raw material;
 - b. daily hours of blending operations;
 - c. calculated average hourly emission rate during each process
5. Provide information on average blending cycle time and volume of raw material used per batch for each product at the facility.
6. Provide copies of the safety data sheets for each raw material containing formaldehyde, methanol, or xylene.

Appendix D

Confidential Business and Personal Privacy Information

Assertion Requirements

You may assert a business confidentiality claim covering any parts of the information requested in the attached Appendix B or Appendix C, as provided in 40 C.F.R. § 2.203(b).

Emission data provided under Section 114 of the CAA, 42 U.S.C. § 7414, is not entitled to confidential treatment under 40 C.F.R. Part 2.

“Emission data” means, with reference to any source of emissions of any substance into the air:

Information necessary to determine the identity, amount, frequency, concentration or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source (or of any pollutant resulting from any emission by the source), or any combination of the foregoing;

Information necessary to determine the identity, amount, frequency, concentration or other characteristics (to the extent related to air quality) of the emissions which, under an applicable standard or limitation, the source was authorized to emit (including to the extent necessary for such purposes, a description of the manner and rate of operation of the source); and

A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

40 C.F.R. § 2.301(a)(2)(i)(A), (B) and (C).

To make a confidentiality claim, submit the requested information and indicate that you are making a claim of confidentiality. Any document for which you make a claim of confidentiality should be marked by attaching a cover sheet stamped or typed with a caption or other suitable form of notice to indicate the intent to claim confidentiality. The stamped or typed caption or other suitable form of notice should employ language such as “trade secret” or “proprietary” or “company confidential” and indicate a date, if any, when the information should no longer be treated as confidential. Information covered by such a claim will be disclosed by EPA only to the extent permitted and by means of the procedures set forth at Section 114(c) of the CAA and 40 C.F.R. Part 2. Allegedly confidential portions of otherwise non-confidential documents should be clearly identified. EPA will construe the failure to furnish a confidentiality claim with your response to the Request to Provide Information as a waiver of that claim, and the information may be made available to the public without further notice to you.

Determining Whether the Information is Entitled to Confidential Treatment

All confidentiality claims are subject to EPA verification and must be made in accordance with 40 C.F.R. § 2.208, which provides in part that you must satisfactorily show that you have taken reasonable measures to protect the confidentiality of the information and that you intend to continue to do so; that the information is not and has not been reasonably obtainable by legitimate means without your consent and that disclosure of the information is likely to cause substantial harm to your business's competitive position.

Pursuant to 40 C.F.R. Part 2, Subpart B, EPA may at any time send you a letter asking that you support your confidential business information (CBI) claim. If you receive such a letter, you must respond within the number of days specified by EPA. Failure to submit your comments within that time would be regarded as a waiver of your confidentiality claim or claims, and EPA may release the information. If you receive such a letter, EPA will ask you to specify which portions of the information you consider confidential **by page, paragraph, and sentence**. Any information not specifically identified as subject to a confidentiality claim may be disclosed to the requestor without further notice to you. For each item or class of information that you identify as being CBI, EPA will ask that you answer the following questions, giving as much detail as possible:

1. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a special event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question number 1?
3. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
4. Is the information contained in any publicly available databases, promotional publications, annual reports or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
5. Has any governmental body made a determination as to confidentiality of the information? If so, please attach a copy of the determination.
6. For each category of information claimed as confidential, **explain with specificity** why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, explain whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.
8. Is there any other information you deem relevant to EPA's determination regarding your claim of business confidentiality?

If you receive a request for a substantiation letter from the EPA, **you bear the burden of substantiating your confidentiality claim.** Conclusory allegations will be given little or no weight in the determination. In substantiating your CBI claim(s), you must bracket all text so claimed and mark it "CBI." Information so designated will be disclosed by EPA only to the extent allowed by and by means of the procedures set forth in 40 C.F.R. Part 2, Subpart B. If you fail to claim the information as confidential, it may be made available to the public without further notice to you.

Personal Privacy Information

Please segregate any personnel, medical and similar files from your responses and include that information on a separate sheet(s) marked as "Personal Privacy Information." Disclosure of such information to the general public may constitute an invasion of privacy.

CERTIFICATE OF MAILING

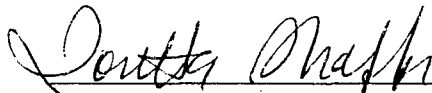
I, Kathy Jones, certify that I sent a Request to Provide Information Pursuant to the Clean Air Act by Certified Mail, Return Receipt Requested, to:

Dow Carter
Leica Biosystems
5205 US Route 12
Richmond, IL 60071

I also certify that I sent a copy of the Request to Provide Information Pursuant to the Clean Air Act by First-Class Mail to:

Eric Jones, Manager
Bureau of Air, Compliance and Enforcement
Illinois Environmental Protection Agency
P.O. Box 19506
Springfield, Illinois 62794

On the 9 day of March 2016.


Kathy Jones, Program Technician
AECAB, PAS

CERTIFIED MAIL RECEIPT NUMBER: 7009 1680 0000 7673 7739